IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA, SOUTHERN DIVISION

IMMOGENE EMODY,	)	
	)	
Plaintiff,	)	**CIVIL ACTION**
	)	
v.	)	**No. CV-02-AR-0111-S**
	)	
MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC.,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

In this unusual case, plaintiff Imogene Emody is suing defendant Medtronic Sofamor Danek USA, Inc. ("MSD"),[1] even though her surgery using MSD's product was a success – her spine indisputably is solidly fused. Her complaint is that, more than four years after her surgery, and after several falls, one of the metal rods implanted in her spine broke and had to be taken out.

This claim fails as a matter of law for several separate and distinct reasons. Of these reasons, one reason in particular – the failure of plaintiff to provide expert testimony to establish medical causation – is such an elemental failing that, in the interests of judicial economy,

[1]MSD manufactured and distributed the "TSRH Spinal System" implanted during plaintiff's operation. Medtronic, Inc. is a remote parent company with nothing to do with this case. As a result, the balance of this motion will refer to MSD only. Nevertheless, the grounds supporting summary judgment in favor of MSD apply equally to Medtronic, Inc. and, therefore, the relief sought in this motion is sought with respect to both defendants.

24

it warrants particular attention. Simply put, although plaintiff has three experts, not one of them opines that she was injured by a purported defect in the rod.[2]

The other independent grounds for summary judgment are no less compelling. MSD and plaintiff agree that the rod here met all applicable ASTM (American Society for Testing and Materials) standards; but plaintiff still asserts a manufacturing defect based upon certain scratches and dents her expert observed in 2002 – after the rod had been bent, cut, implanted for four years and removed. This claim fails because there is no evidence the alleged defects existed at the time of sale.

Component breakage as occurred here is an inherent risk of any metal implant. The spinal rod MSD made lasted far longer than normally necessary for spinal fusion to occur; plaintiff's spine did fuse; and she fell several times before the rod finally broke. Under the Alabama Extended Manufacturers Liability Doctrine ("AEMLD"), prescription medical devices are unavoidably unsafe products, and where inherent risks are at issue, the only other permissible liability theory is inadequate warning.

Plaintiff's warning claim is a vague allegation that MSD "failed to warn plaintiff of the dangers" of the TSRH system. Plaintiff's Answers to Defendants' Interrogatories, No. 24 (attached as Exhibit A). Plaintiff's premise is wrong. Under the learned intermediary rule, MSD only had to warn plaintiff's prescribing physician, J. Stanford Faulkner, Jr., M.D., not plaintiff.

Moreover, plaintiff's warning claim fails regardless of the learned intermediary rule. Plaintiff – herself – already knew from earlier failed back surgery that spinal instrumentation can require additional surgery to remove it. Nor can plaintiff complain that the rod was not

[2]Should the Court grant this aspect of MSD's motion, the additional independent reasons detailed in this motion would become moot, or at most would simply provide alternative grounds for summary judgment.

removed once she achieved fusion. For three years, during which her spine successfully fused, she did not see Dr. Faulkner. Dr. Faulkner had no opportunity to remove the rod before it broke.

As for warnings to Dr. Faulkner, MSD's package insert repeatedly discussed all relevant risks. MSD recommended removal of the device after fusion, but plaintiff's failure to see Dr. Faulkner made that impossible. Moreover Dr. Faulkner had used instrumentation in spinal fusion surgery over 1,000 times before he operated on plaintiff. He knew about all the risks independently, from his own extensive experience, and did not rely upon MSD's warnings.

Plaintiff also asserts warranty claims. These claims are barred by the applicable statute of limitations, and they state no claim separate from plaintiff's product liability claims.

Thus, aside from plaintiff's inability to establish medical causation, MSD is entitled to summary judgment because: (1) plaintiff has no evidence of a manufacturing defect at time of sale; (2) given plaintiff's own knowledge and conduct, no warning could have changed the outcome; (3) MSD's warnings were adequate as a matter of law; and (4) Dr. Faulkner's non-reliance upon MSD's warnings severs any causal link.

In support of this motion, MSD offers the following:

- Plaintiff's Answers to Defendants' Interrogatories, attached as Exhibit A.
- Excerpted portions of Deposition of J. Stanford Faulkner, M.D., attached as Exhibit B.
- MSD Supplemental Interrogatory Responses, attached as Exhibit C.
- Affidavit of James L. Ritter, attached as Exhibit D.
- Report of Raymond Thompson, Ph.D., titled "Chemistry," "Hardness," and "Metallographic Analysis", attached as Exhibit E.
- Cooper (10/31/02) Letter to Levin, attached as Exhibit F.
- Dr. Sellers-Bok's medical records concerning plaintiff, attached as Exhibit G.

- Picture of device components showing severed screw heads, attached as Exhibit H.
- Plaintiff's Amended Complaint, attached as Exhibit I.

STATEMENT OF FACTS

I. Background

This is a case involving a spinal rod that remained in plaintiff's body without problem for almost four years, from November 1996, until October 2000. Nobody knows exactly when it broke, because plaintiff stopped seeing her surgeon, J. Stanford Faulkner, Jr., M.D., for three years. Deposition of J. Stanford Faulkner, M.D., at 49-50 (excerpted portions attached as Exhibit B) ("Faulkner Dep."). Plaintiff reported the broken rod to Dr. Faulkner on October 11, 2000. Id. at 49. Despite the break, plaintiff's instrumented spinal fusion surgery,[3] involving implantation of the rod, was a success because plaintiff's spine successfully fused sometime during the period that she was not seeing Dr. Faulkner. Id. at 72-73.

II. Plaintiff's Medical Condition And Surgery

Plaintiff first saw Dr. Faulkner on October 4, 1996, for chronic pain despite four prior back operations. Faulkner Dep. at 29-30. A 1994 spinal fusion attempt had failed, requiring more surgery in 1995 to remove implanted spinal instrumentation. Id. at 31-32. Dr. Faulkner diagnosed "failed back syndrome," which is "continue[d back]. . .pain that is unrelieved by. . . surgeries." Id. at 41. Plaintiff suffered from "spinal stenosis" and "degenerative scoliosis." Id. at 30.[4]

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[3]Spinal fusion surgery "immobilize[s] segments in the spine and make[s] them grow together, segments that are either unstable or causing pain from the motion they are having." Faulkner Dep. at 12.

[4]Stenosis is "a narrowing of the spinal canal." Faulkner Dep. at 30. Degenerative scoliosis occurs when "the ligaments and discs in the spine degenerate, wear and tear, and start collapsing and letting the spine curve." Id. at 30-31. Plaintiff was a "scoliosis case." Id. at 93.

Dr. Faulkner recommended a different kind of back surgery, "posterior lumbar interbody fusion," across five levels of plaintiff's spine, from L1 through L5.[5] Faulkner Dep. at 33, 41, 71. Spinal fusion surgery "immobilize[s] segments in the spine and make[s] them grow together, segments that are either unstable or causing pain from the motion they are having." Id. at 11.[6] "Interbody" surgery is "not just a simple posterior fusion" like plaintiff had in 1994. Id. at 34. Rather, during interbody fusion entire discs are removed and replaced with "bone or. . .bone substitute." Id. at 33. Plaintiff's surgery occurred on November 13, 1996. Id. at 43.[7]

Spinal instrumentation is "an internal support and a brace." Faulkner Dep. at 12. It "holds the spine in the position we want to keep it. . .while it's fusing." Id. at 72. Instrumentation: (1) reduces the length of hospital stays from months to days, and (2) increases the likelihood that fusion will occur. Id. at 12-13, 16. Dr. Faulkner uses spinal instrumentation in 98% of the spinal fusion surgery he performs. Id. at 14. He prefers MSD's TSRH Spinal System,

> because it's good in my hands. I can put it in easily. It's very rigid. It's strong. It's a low enough profile that it doesn't get in the way of the fusion we are trying to achieve.

Id. at 19. Plaintiff required a "long fusion," so Dr. Faulkner chose "a thicker rod." Id. at 71.[8]

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[5]Each spinal vertebra is numbered by standard medical convention. The lower, or "lumbar" section of the spine has 5 vertebrae, numbered from L1 (the farthest up the body) to L5 (the lowest down, resting on the sacrum). An L1-L5 fusion is a fusion of the entire lumbar spine.

[6]Another benefit of spinal fusion surgery in scoliosis patients is that it reduces the spinal curvature caused by the disease and makes the spine "straighter." Faulkner Dep. at 42. The surgery restored plaintiff to "perfect posture." Id. at 44.

[7]Plaintiff makes no claim that her surgery was "not appropriate." Plaintiff's Answers to Defendants' Interrogatories, No. 19 (Ex. A). Nor does she claim any "alternative" surgical procedure would have been "a safer or more effective treatment." Id. at No. 25.

[8]Dr. Faulkner chose quarter-inch, rather than three-sixteenth inch, thick rods. Faulkner Dep. at 42, 71.

After surgery, plaintiff saw Dr. Faulkner for several routine follow-up visits until August 20, 1997. Faulkner Dep. at 44-47, 49. On August 20, 1997, while "[i]t looked like the fusion was progressing well," plaintiff's spine had not "totally" fused. Id. at 47, 55. Dr. Faulkner scheduled plaintiff for another appointment in a year. Id. at 49. Plaintiff did not return – and did not see Dr. Faulkner at all for the next three years, until October 11, 2000. Id. Because of this long gap, nobody knows exactly when her spine fused. Id. at 72-73.

On October 11, 2000, almost four years post-surgery, plaintiff returned to Dr. Faulkner complaining of increased back pain. Faulkner Dep. at 49. Dr. Faulkner diagnosed, and later confirmed by direct observation, that she had a solid fusion and a "nondisplaced" rod fracture. Id. at 52, 54-55, 58, 60, 72, 77.[9]

Dr. Faulkner removed the instrumentation, including the broken rod, in January 2001. Id. at 77. Plaintiff told Dr. Faulkner that she had suffered "numerous falls" while the rod was implanted. Id. at 49.[10] From the rod's condition, Dr. Faulkner testified it could well have broken as a result of "severe direct trauma," from one of plaintiff's falls. Faulkner Dep. at 39.

> [I]t could have been from trauma. A quarter-inch rod would – you would be hard pressed to break a quarter-inch rod on one side without a gross nonunion. So, I think it had to have been from trauma.

Id. at 56.

> If she had – if you had a solid fusion, I think you would probably need some direct trauma on that to break it. If it occurred early on before the fusion had become solid, any fall could have really done it.

Id. at 79.

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[9]"[Nondisplaced] means I can see the break because there's a small gap, less than a millimeter gap." Faulkner Dep. at 53.

[10]Plaintiff had a history of falls before she ceased keeping her appointments with Dr. Faulkner in 1997. She had fallen while still in the hospital, and again while "climbing over a fence." Faulkner Dep. at 43, 47.

Plaintiff brought this action on December 14, 2001. Originally, there were three defendants: (1) Medtronic, Inc.; (2) Sofamor Danek Group, Inc.; and (3) Medtronic Sofamor Danek, (Inc.). On March 5, 2002, plaintiffs' complaint was amended to substitute MSD for the latter two original parties, leaving Medtronic, Inc. and MSD as the two defendants in the case.

III. Dr. Faulkner's Extensive Knowledge And Experience

Dr. Faulkner graduated from the University of South Alabama College of Medicine in 1981, and was board certified in orthopedics in 1990. Faulkner Dep. at 7-8. He learned about spinal instrumentation during his residency, and had performed instrumented spinal fusion surgery as a lead surgeon since 1988. Id. at 9, 61. When he first operated on plaintiff's spine, Dr. Faulkner had performed instrumented spinal fusion surgery well over 1,000 times, probably over 2,000 times. Id. at 10, 70. He had been using TSRH instrumentation since 1989. Id. at 18.

Before plaintiff's surgery, Dr. Faulkner knew the risks of instrumented spinal fusion surgery, including: the "possibility of breakage of any of the components," the possibility that "pain might continue" or that "additional or new pain might result," the possibility of "neurological damage, including loss of neurologic function," the possibility "that additional surgery might be required," and "that scar tissue might form." Faulkner Dep. at 14-15.

With experience in over 1,000 prior surgeries, Dr. Faulkner made "independent assessments of how the TSRH system performed." Faulkner Dep. at 66-67. He knew components could break and "sometimes" had to be removed. Id. at 14, 57. Even without breakage, about 20% of his patients required removal of instrumentation, usually due to pain or discomfort. Id. at 65, 70, 96. Since 80% of his patients had no such complaints, his "intention was to leave them [instrumented] forever," since "[i]f the fusion is successful, and they are not having pain,

there's no need to take them out." Id. at 65; see id. at 77 ("from that point on it just sits there and coexists with the body").

Before operating on plaintiff, Dr. Faulkner considered himself "adequately and appropriately informed as to the risks and benefits of using TSRH spinal instrumentation." Faulkner Dep. at 17. Dr. Faulkner did not obtain his information from MSD:

> The sources of this type of information are in medical books, textbooks. They are in journals, spine journals, orthopedic journals, orthopedic texts, spinal texts. We get newsletters that we discuss. We talk among peers. There are discussions at meetings that we have.

Id. at 16-17. His other source of information was his "training" and extensive "personal experience." Id. at 17. He never received training from MSD, and did not rely upon information from MSD. Id. at 61 (generally); 64 (about "how long these rods are to last").[11]

Dr. Faulkner has learned nothing since November 1999 that causes him to question his decision to perform instrumented spinal fusion surgery on plaintiff, nor has he reduced his use of TSRH instrumentation – which he continues to use exclusively. Faulkner Dep. at 10-11, 19. MSD made no misrepresentations about the TSRH system. Id. at 26-27.

IV. The TSRH Titanium Spinal Implant System

The TSRH Spinal System is a multi-component medical device consisting of rods, cross-links, hooks, and screws in several sizes. Faulkner Dep. at 20. For each patient, the surgeon selects the size and configuration of the component parts to use. Id. at 21. The surgeon also chooses between stainless steel and titanium models. Id. at 23. Dr. Faulkner prefers titanium "because it's not as stiff as stainless steel." Id. From the various TSRH components, Dr. Faulkner constructed a "custom made" implant for plaintiff. Id. at 24.

[11]Dr. Faulkner's contact with MSD personnel was to ensure an adequate supply of TSRH component parts and to resolve occasional problems with tools. Faulkner Dep. at 62.

Plaintiff's counsel found the number 82836 on the rod. MSD Supplemental Interrogatory Responses (attached as Exhibit C). Order #82836 is for titanium TSRH quarter-inch rods, MSD catalogue #828-083. Affidavit of James L. Ritter ¶3 (attached as Exhibit D) ("Ritter Aff."). Specifications for this rod require ASTM standard F-136 titanium alloy 6Al-4V, and shot peening. Id. ¶5 & Ex. 3. The alloy used in MSD order #82836 was tested twice, and conformed in all respects to ASTM standards. Id. ¶¶7-9 & Exs. 4-5. After this litigation began, plaintiff's metallurgical expert, Raymond Thompson, Ph.D., retested samples of the rod at issue. Dr. Thompson's tests likewise confirmed conformity to ASTM standards. Report of Raymond Thompson, Ph.D., at pp. 4-6 ("Chemistry," "Hardness," and "Metallographic Analysis") (attached as Exhibit E).

The TSRH Spinal System also comes with a package insert. Ritter Aff. ¶4 & Ex. 2; Faulkner Dep. at 24-25. Dr. Faulkner neither read nor relied upon the information in MSD's package insert when he operated on plaintiff:

Q. Do you normally review the package insert?

A. I haven't looked at one in years, but I have read them before.

Q. Would it be fair to say that you did not rely on the package insert in performing surgery on Ms. Emody?

A. Yes.

Id. at 25.

The relevant 1996 TSRH package insert, Ritter Aff. at Ex. 2, mentions every device risk plaintiff claims she encountered: marring of the rod, component breakage, return of pain, falls. The insert also discusses the need for a second operation to remove the instrumentation. Concerning marring breakage, renewed pain, and falls, the package insert states:

> All of the potential adverse events associated with spinal surgery without instrumentation are possible. With instrumentation, the list of potential adverse events includes but is not limited to:
>
> * * * *
>
> 3. . . .[B]reakage of any or all of the components. . . .
>
> * * * *
>
> 10. . . .[D]evelopment of pain. . . .

Id. at "Potential Adverse Events."

> Potential risks identified with the use of this device system, which may require additional surgery, include:
>
> – device component fracture

Id. at "Warnings and Precautions."

> 3. . . .The implants should not be scratched or damaged.

Id. at "Preoperative."

> 1. . . .The patient should be warned to avoid falls. . . .

Id. at "Postoperative."

Concerning device removal after fusion, and the possibility of additional surgery, the package insert states:

> The system is intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass.

Id. at "Purpose."

> The TSRH Spinal System, when us[ed]. . .as pedicle screws is intended only for patients. . .(d) who are having the device removed after the development of a solid fusion mass.

Id. at "Indications."

> **NOTE**: Additional surgery may be necessary to correct some of these anticipated adverse reactions.

Id. at "Potential Adverse Effects."

> 6. The TSRH Spinal System implants are internal fixation devices that are intended to be removed. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and must be removed. . . . If the device is not removed following completion of its intended use, any of the following complications may occur:. . .(3) Risk of injury from postoperative trauma, (4) bending, loosening and/or breakage. . ., (5) Pain, discomfort or abnormal sensations due to the presence of the device. . . .

Id. at "Postoperative."[12]

V. Plaintiff's Expert Witnesses

Pursuant to the Court's amended scheduling order, plaintiff was required to submit all her expert reports by November 8, 2002. On October 31, 2002, plaintiff's counsel stated that he would use as medical experts: (1) her implanting surgeon, Dr. Faulkner, with his deposition serving as an expert report, and (2) a psychiatrist, Dr. Margaret Sellers-Bok, M.D. Cooper (10/31/02) Letter to Levin (attached as Exhibit F). Counsel provided Dr. Sellers-Bok's medical records concerning plaintiff (attached as Exhibit G). On November 7, 2002 plaintiff submitted the metallurgical report of Raymond Thompson, P.E. (Exhibit E).

A. Dr. Faulkner's Opinions

During his deposition, Dr. Faulkner offered a number of opinions concerning the rod that broke. These opinions were all to a reasonable degree of medical certainty. Faulkner Dep. at 66. Dr. Faulkner explained that, any time weight-bearing instrumentation is implanted in the body, there is a risk it will break. "It takes anywhere from six months to a year and a half" for spinal vertebrae to fuse together (id. at 72), and during that time there is a "race" between

[12]While MSD recommends removal of TSRH instrumentation following successful fusion, Dr. Faulkner does not routinely do this because he thinks the risks of additional surgery outweigh the risks of leaving the rods in place in the great majority (80%) of patients. Faulkner Dep. at 63-65.

completion of the fusion and the constant stress that the body places on instrumentation that is serving as a back brace:

> [W]hen we are doing a fusion there's a race between the fusion becoming solid and something coming loose or breaking. . . . The screws can loosen, the screws can break, rods can break. If the fusion doesn't occur and there's motion, then something is going to give.

Id. at 37.[13]

The rod here lasted some four years – far longer than necessary for fusion to occur. Faulkner Dep. at 49, 79. During this time plaintiff reported "numerous falls." Id. at 49. Thus, Dr. Faulkner did not believe the rod was defective in any way. Dr. Faulkner was asked whether, in his opinion, the TSRH rod was defectively designed or manufactured. He stated that the rod had no defects in either its design or manufacture:

> Q. Do you believe the components you implanted in Ms. Emody, and specifically the rods, were poorly manufactured?
>
> A. No.
>
> Q. Are you aware of any manufacturing problems or defects in the components you implanted in Ms. Emody?
>
> A. No.
>
> Q. And specifically the rods?
>
> A. No.
>
> Q. Do you believe the components that you implanted in Ms. Emody – and pay special attention to the rods – were poorly designed?
>
> A. No.
>
> Q. Are you aware of any design problems or defects in the components which you implanted in Ms. Emody and specifically in the rods?

[13] See Faulkner Dep. at 38: "But any metal that bends enough will break eventually. If you keep loading a metal and it bends, it will break. So, if you have a non-union, then either the bones will give and make room for the metal, or if the bones don't give then the metal will give. And that's usually in breakage."

A. No.

Faulkner Dep. at 27-28.

Dr. Faulkner was also asked whether, in his opinion, MSD had provided inadequate warnings with respect to the TSRH system. Dr. Faulkner opined that he was adequately informed about the risks and benefits of spinal instrumentation:

Q. Do you believe that the components that you implanted in Ms. Emody were components about which you were adequately warned as to the risks and benefits?

A. Yes.

Q. Do you believe that you were adequately informed as to the risks and benefits of the TSRH system that you implanted in Ms. Emody in November of 1996?

A. Yes.

Faulkner Dep. at 28.

Dr. Faulkner was asked whether he knew of any defects of any sort in the TSRH rod. He replied that he knew of none:

Q. Was there anything at all that was wrong with the TSRH rods or any of the other components of the system that you implanted in Ms. Emody in November of 1996?

A. No.

Faulkner Dep. at 28.

Finally Dr. Faulkner was asked for his causation opinions. Dr. Faulkner opined both that no defect caused the rod to break and that no defect caused any injury to plaintiff:

Q. Do you believe that Ms. Emody's rod broke because of a defect in the rod?

A. No.

* * * *

Q. Do you believe that the rods or any of the components caused any injury to Ms. Emody?

A. No.

Faulkner Dep. at 28-29.

When plaintiff's spine fused "the instrumentation had done its intended purpose." Id. at 47; see id. at 96 ("Q. Did the TSRH components do their job here? A. Yes."). Dr. Faulkner further opined that the broken rod was harmless:

Q. . . .What is it doing?

A. It wasn't doing anything.

Q. Was it impinging on any nerves?

A. No.

Q. Was it jutting out into the body in any way?

A. No.

Id. at 54-55.

B. Dr. Sellers-Bok's Records

Dr. Sellers-Bok, plaintiff's other designated medical expert, is a psychiatrist who has been seeing plaintiff for the same mental conditions, depression, anxiety, and psychotic symptoms, since June 15, 1999 – a year before plaintiff was found to have a broken rod. See Sellers-Bok medical records (Ex. G).[14] Dr. Sellers-Bok's notes do not mention plaintiff being in "pain" of any sort before October 20, 1999, and do not mention her back before July 31, 2001. Id. at unsigned notes bearing those dates. They nowhere mention the TSRH rod at issue; or that

[14]Dr. Sellers-Boks' records of plaintiff's treatment are attached in the same manner as they were produced by plaintiff.

the rod broke. Id. Dr. Sellers-Bok's records, even if they could be considered an expert report,[15] thus do not contain any medical causation opinions concerning the rod.

C. Dr. Thompson's Opinions

As discussed above, Dr. Thompson subjected portions of the rod to objective metallurgical testing for composition, hardness, and microstructure. Dr. Thompson's objective tests establish that the rod met ASTM Standards for chemistry (Thompson Report (Ex. E) at 4); for hardness (id. at 4-5); and for microstructure. Id. at 5-6.

However, based on a subjective visual inspection, Dr. Thompson opines that the rod was "substandard in respect to surface finish leading to multiple cracking, failure, and reduced service life." Id. at 1.[16] Dr. Thompson describes seeing "several impressions/scratches (grooves, machine marks)":

> There were grooves/scratches that ran circumferentially around the rod. There were small oval shaped flat areas on the concave side of the bend in the rod. Small areas of longitudinal grooves/impression were located on the concave side of the bend that coincided with the oval flat areas.

Id. at 3.

But when Dr. Thompson examined the rod surface in 2002, it had been out of MSD's hands for some six years. Dr. Faulkner testified that before implantation, he first cut and shaped the rod to match plaintiff's unique anatomy:

> We measure the length we need and then cut it. Then I take what we call a French bender, which is a tool that will curve and bend it, and contour the rod to fit the particular back.

[15]These office notes are unsigned, unauthenticated and unsworn hearsay. They cannot constitute an expert report under Fed. R. Civ. P. 26(a)(2)(B).

[16]Dr. Thompson does not identify the standard, if any, by which he claims the rod's finish is "substandard."

Faulkner Dep. at 21. The rod then spent four years in plaintiff's body, enduring repeated stresses before plaintiff's spine fused (id. at 37), and also being subjected to "trauma" from plaintiff's falls both before and after her spine successfully fused. Id. at 47, 49, 56, 79. After the break was discovered, the rod and other components were removed by a process that broke the heads off of several of the screws. Id. at 56; see Picture of device components showing severed screw heads (attached as Exhibit H).[17]

Of equal importance, Dr. Thompson never opines that either the surface finish or the various markings are product "defects." Assuming that is what he means to say, Dr. Thompson does not opine that any of that these defects were the medical cause of injury – nor could he since he is an engineer, not a medical doctor. Nowhere in his nine-page report does Dr. Thompson state that plaintiff's outcome would have been any different – *i.e.*, that the rod would not have broken – had the claimed defects not been present.

ARGUMENT

I. MSD Is Entitled To Summary Judgment Because Plaintiff Has Offered No Expert Testimony To Establish Medical Causation.

An "essential element" of all product liability claims is expert testimony that a defect in the rod was the medical cause of plaintiff's claimed injuries. Tidwell v. Upjohn Co., 626 So. 2d 1297, 1299 (Ala. 1993). Here, plaintiff must have evidence that a defect in the rod caused it to break, and that the broken rod caused her claimed injuries. Plaintiff must prove causation by expert testimony because "recovery cannot be predicated on injury alone." Verchot v. General Motors Corp., 812 So. 2d 296, 301 (Ala. 2001) (emphasis original) (citation and

[17]This photograph was produced by plaintiff's counsel on October 31, 2002.

quotation marks omitted). Expert evidence is "required" where, as here, a product is "complex and technical." Brooks v. Colonial Chevrolet-Buick, Inc., 579 So. 2d 1328, 1332 (Ala. 1991).

> The evidence and testimony likely to prove. . . the defect's link to the Defendant, depend upon the nature of the facts; but ordinarily, expert testimony is required because of the complex and technical nature of the commodity.

Verchot, 812 So. 2d at 302 (emphasis original) (citation and quotation marks omitted). A plaintiff's failure to establish a causal defect by expert testimony warrants entry of summary judgment. See, e.g., Slay v. Keller Industries, Inc., 823 So. 2d 623, 626 (Ala. 2001) (affirming summary judgment where plaintiff's expert did not testify that the product had a defect that caused injury); Ex parte Diversey Corp., 742 So. 2d 1250, 1254-55 (Ala. 1999) (reinstating summary judgment where plaintiff had no proper expert testimony on causation).

Here plaintiff offers the expert report of Dr. Thompson, the deposition of Dr. Faulkner and the records of Dr. Sellers-Bok as the sum total of her expert testimony. None of these witnesses offer any opinion that a defect in the rod caused injury to plaintiff. Dr. Thompson, an engineer, opines that "substandard" surface finish led to "multiple cracking, failure, and reduced service life." Thompson Report at 1. But plaintiff's medical expert points out, the rod had spent "four years" in plaintiff's body, Faulkner Dep. at 49,[18] and had been subjected to "numerous falls" before it broke. Id. The rod remained intact for more than twice as long as the maximum time (18 months) that fusion ordinarily takes to occur. Id. at 72. Thus the rod had already served for double its anticipated useful life when plaintiff reported it broken. There is no opinion in Dr. Thompson's report that a non-defective rod, without a supposedly "substandard" surface finished would have fared any better.

[18] See also Sellers-Bok office note dated July 31, 2001 (first mention of pain relating to back surgery).

Moreover, Dr. Thompson is an engineer, not a medical doctor. He does not purport to opine on what injuries plaintiff suffered as a consequence of the broken rod. While testimony by a medical doctor is not strictly required, there must be medical testimony of some sort to establish medical causation. Tidwell, supra; Knapp v. Wilkins, 786 So. 2d 457, 462-63 (Ala. 2000). Neither of the two medical doctors plaintiff lists as her expert witnesses opine that the broken rod caused any injury to plaintiff.

The medical records plaintiff offers from her psychiatrist, Dr. Sellers-Bok, are simply irrelevant. Those records (Ex. G) do not mention the TSRH rod, its condition, or how that condition has anything to do with plaintiff's complaints. Nothing in Dr. Sellers-Bok's notes that can be considered an opinion about anything related to the product in this case.

Dr. Faulkner's testimony is even more devastating to plaintiff's case. Far from supporting any of plaintiff's contentions, Dr. Faulkner repudiated those claims under oath. Dr. Faulkner affirmatively testified that the rod was not defective, that he was adequately warned, that the rod fracture was "nondisplaced" and "wasn't doing anything," that no defect caused the rod to break and that no defect caused any injury to Plaintiff. Faulkner Dep. at 27-29, 54-55 (emphasis added). Dr. Faulkner is plaintiff's designated medical expert; plaintiff has offered no other medical opinions. Because plaintiff's own expert witness has testified that the TSRH rod was not the medical cause of any injury, MSD is entitled to summary judgment.

Although she has named three experts, plaintiff still has no evidence that she was injured by a purported defect in the rod. Plaintiff's failure of proof – indeed her offer of Dr. Faulkner's affirmative expert testimony that no causal defect exists – requires the entry of summary judgment for defendants and the dismissal of plaintiff's complaint with prejudice.

II. As A Matter of Law, Plaintiff Has No Evidence Establishing Any Defect In The TSRH Rod

Apart from plaintiff's lack of any expert testimony, the undisputed facts establish, as a matter of law, that plaintiff cannot prove any defect in MSD's TSRH rod. There is no evidence of a manufacturing defect; the rod is an "unavoidably unsafe" product under Alabama law, thereby precluding design defect liability; and MSD's warnings were adequate as a matter of law and, in any event, Dr. Faulkner did not rely on them.

A. Under The Unavoidably Unsafe Product Doctrine, Only Warning Defect Claims Can Be Brought Against Manufacturers Of Properly Prepared Prescription Medical Products.

The TSRH spinal rod is a prescription-only medical device. "Federal law (U.S.A.) restricts these devices to sale by or on the order of a physician." TSRH Package Insert at "Caution." Ritter Aff. at Ex. 2. Under the AEMLD, only warning defects can be asserted against manufacturers of prescription medical products. Such products "are considered unavoidably unsafe products, [and] they are defective only when not accompanied by an adequate warning." Tatum v. Schering Corp., 795 F.2d 925, 926 (11th Cir. 1986) (applying Alabama law); see Lowe v. Metabolife Int'l, Inc., 206 F. Supp. 2d 1195, 1201 (S.D. Ala. 2002) (AEMLD "takes into account the user's awareness of the danger and that awareness may be enlightened by a warning"; all drug warning claims "subsumed" by AEMLD).

The Alabama Supreme Court, in Stone v. Smith, Kline & French Laboratories, 447 So. 2d 1301 (Ala. 1984), established this limitation by adopting the "unavoidably unsafe" product standard of Restatement (Second) of Torts §402A, comment k (1965) for prescription medical products. Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Stone, 447 So. 2d at 1303 n.1 (quoting comment k).

> Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

Id. (emphasis original in Stone).

The Stone court held that comment k was "rightly" applied to a prescription drug. Id. at 1303. Inherent product risks were not "defects" in and of themselves, but rather were characteristics that required proper warnings:

> [W]e agree, that in the case of an "unavoidably unsafe" yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably dangerous.

Id. at 1304 (citations omitted). Since Stone was decided in 1984, no Alabama court has entertained any AEMLD claim involving a prescription medical product that was not warning related.

Nor should any distinction be drawn between the prescription drugs in Stone, Tatum, and Lowe and the prescription medical device here. Comment k applies to "drugs, vaccines, **and the like**." Stone, 447 So. 2d at 1303 n.1 (quoting comment k) (emphasis added). The Alabama Supreme Court applies the unavoidably unsafe product doctrine expansively, extending it to all inherently dangerous products distributed through "professional 'middlemen'":

> Because there are many similarities between this case and these other Section 402A, comment k cases, it seems reasonable to extend comment k to an effective dry cleaning solvent. . . . Each involves the distribution of a product that, no matter how carefully manufactured or used, can conceivably cause physical injury. Each involves a commercial situation in which the identity of the ultimate user of the product is unknown to the manufacturer. Each involves a professional "middleman" between the manufacturer and the ultimate user, a middlemen who is by training, experience, and instruction familiar with the risks inherent in the use of the product.

Purvis v. PPG Industries, Inc., 502 So. 2d 714, 718 (Ala. 1987).

Since Purvis extends the unavoidably unsafe product doctrine to cases involving non-medical products, the doctrine easily encompasses the inherent risks of prescription medical

devices. No jurisdiction in the country has distinguished between prescription medical devices and prescription drugs in applying the unavoidably unsafe product doctrine of comment k.[19]

B. MSD Is Entitled To Summary Judgment Against Plaintiff's Claim That The TSRH Rod Was Improperly Prepared.

To avoid the limitations of the unavoidably unsafe product doctrine, plaintiff asserts, through Dr. Thompson, that the rod had a "substandard" surface finish. Thompson Report at 1. This claim fails for two reasons.

First, Dr. Thompson examined a rod that was six years old and had been subjected to many stresses that could have degraded its finish since leaving MSD's hands. In the operating room it was put in a "French bender" and was cut and bent by Dr. Faulkner. Faulkner Dep. at 21. The rod was then in plaintiff's spine for four years. Until plaintiff's spine fused, it endured the constant cyclic stress of supporting plaintiff's weight. Id. at 37. Both before and after fusion, the rod was also subject to "direct trauma" from plaintiff's "numerous falls." Id. at 49, 79.

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[19]The Restatement (Third) of Torts, Products Liability §6 (1998) treats drugs and medical devices the same. Likewise, the following jurisdictions have determined that comment k applies equally to both prescription medical products and prescription drugs:

California: Hufft v. Horowitz, 5 Cal. Rptr. 2d 377, 384 (Cal. App. 4th Dist. 1992).
Florida: Adams v. G.D. Searle & Co., 576 So. 2d 728, 731-33 (Fla. App.), review denied, 589 So. 2d 290 (Fla. 1991).
Illinois: Greenberg v. Michael Reese Hospital, 415 N.E.2d 390, 394-95 (Ill. 1980).
Indiana: Parks v. Danek Medical, Inc., 1999 WL 1129706, at *6 (N.D. Ind. Jun 17, 1999).
Kentucky: Clark v. Danek Medical, Inc., 1999 WL 613316, at *4 (W.D. Ky. Mar. 29, 1999).
Massachusetts: Lareau v. Page, 840 F. Supp. 920, 933 (D. Mass. 1993), aff'd, 39 F.3d 384 (1st Cir. Mass 1994).
New Mexico: Perfetti v. McGahn Medical, 662 P.2d 646, 649-50 (N.M. App.), cert. denied, 662 P.2d 645 (N.M. 1983).
Oklahoma: Edwards v. Basel Pharmaceuticals, 933 P.2d 298, 300 (Okla. 1997).
Pennsylvania: Murray v. Synthes U.S.A., Inc., 1999 WL 672937, at *7 (E.D. Pa., Aug. 23 1999); Burton v. Danek Medical, Inc., 1999 WL 118020, at *6 (E.D. Pa. Mar. 1, 1999); Taylor v. Danek Medical, Inc., 1998 WL 962062, at *7 (E.D. Pa. Dec. 29, 1998).
South Carolina: Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230 (4th Cir. 1984) (applying South Carolina law).
Tennessee: Harwell v. American Medical Systems, Inc., 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992).
Washington: Terhune v. A.H. Robins Co., 577 P.2d 975, 980 (Wash. 1978).

Finally, during removal, the rod received still more rough handling – sufficient to break the heads off of several of the screws that had held the rod in place. See Ex. H.

The AEMLD, "is a fault-based cause of action," thus a plaintiff "must affirmatively show that the product was sold with a defect or in a defective condition." Jordan v. General Motors Corp., 581 So. 2d 835, 836-37 (Ala. 1991). Lack of "substantial evidence" that the claimed defect existed when the manufacturer sold the product is fatal to a plaintiff's claim:

> [T]he plaintiff bears the burden of proving that the product was in a defective condition when it left the defendant's control. Without evidence to support the conclusion that the product was defective and/or unreasonably dangerous when it left the hands of the seller, the burden is not sustained.

Jordan, 581 So. 2d at 837 (citation omitted). An opinion that "merely speculates that any alleged defect in the [product] occurred while in the seller's control. . .is completely insufficient to warrant the submission of a case to the jury." Allstate Insurance Co. v. Mitsubishi Elecs. Am., 709 So. 2d 1306, 1309 (Ala. Civ. App. 1998) (citation and quotation marks omitted).

Dr. Thompson's report provides no factual basis for concluding that the "scratches", "impressions" and other assorted imperfections he saw in 2002 existed when MSD sold the rod in 1996. Rather, the undisputed facts demonstrate that the rod was subjected to potentially damaging forces on numerous occasions that could have created these same markings after sale. MSD is entitled to summary judgment against plaintiff's manufacturing defect claim because plaintiff has failed to carry her burden of establishing a defect at the time of sale.

Second, Dr. Thompson's report cannot withstand summary judgment because his assertion of "substandard" surface finish is itself standardless. Dr. Thompson's report does not reveal the standard against which he declares the rod to be substandard. Thus his report is inadmissible and ineffective to oppose summary judgment. Slay, 823 So. 2d at 626. In Slay, an

expert claimed a ladder was defective because it was "underdesigned" but "offered no test results or factual information to support his belief." Id. at 625. The Alabama Supreme Court held:

> Mere assertions of belief, without any supporting research, testing, or experiments, cannot qualify as proper expert scientific testimony. . . . A party opposing a motion for summary judgment. . .must present facts, not merely inferences based upon belief, that counter the facts offered in support of the motion.

Id. at 626 (citation and quotation marks omitted).

Dr. Thompson's conclusory declaration that the rod's finish was "substandard" is even less cognizable than the opinion excluded in Slay. While in Slay there were no tests, Dr. Thompson conducted several objective metallurgical tests on the rod – and those tests affirmatively demonstrated that the rod was not defective in composition, hardness or metallography. Thompson Report at 4-6. Only after his objective tests showed no defect, did Dr. Thompson fall back upon a subjective visual inspection, and declare the rod's finish "substandard" by standards known only to himself. An expert's defect opinion must be based upon "methods, or procedures that have gained general acceptance in the field in which the expert is testifying." Slay, 823 So. 2d at 626. Dr. Thompson eyeballs-only pronouncement of a "substandard" finish is based upon no discernable methodology, procedure, or standards. It is inadmissible under Slay and cannot prevent summary judgment.

C. MSD Is Entitled To Summary Judgment Against Plaintiff's Warning Defect Claim.

There being no credible evidence that the TSRH rod was not "properly prepared," it is an unavoidably unsafe product for which MSD can be liable, if at all, only on a claim of inadequate warnings. Stone, 447 So. 2d at 1303-04 & n.1.[20] Thus, the only claim plaintiff can

[20]In addition to Dr. Thompson's tests, the composition of the TSRH rod was tested twice before MSD sold it and both times met ASTM standards. Ritter Aff. ¶¶5, 8-9 & Exs. 3-5.

pursue in this litigation is a challenge to the adequacy of MSD's warnings concerning the TSRH rod. On the undisputed facts, and under the controlling law, that claim fails, and MSD is entitled to summary judgment.

1. Plaintiff's Own Knowledge And Own Conduct Bar Any Claim For Inadequate Warning.

There are several reasons why plaintiff cannot present a genuine issue of material fact concerning MSD's warnings. First, and foremost, are her own actions and medical history. Prior to her surgery with MSD's device, plaintiff had already experienced failed instrumented spinal fusion surgery and device removal in 1994-95. Faulkner Dep. at 31-32. She thus already knew that fusion surgery might not cure her back pain and that the instrumentation may have to be removed. Plaintiff cannot claim ignorance of her own medical history, so she had to know in November, 1996 that additional surgery was a possibility and that spinal fusion surgery does not always cure back pain.

The AEMLD imposes no duty to warn people about things they already know. Defendants "d[o] not have a duty to provide [plaintiffs] with a warning of a danger of which they already were, or had reason to be, aware." Ex parte Chevron Chem. Co., 720 So. 2d 922, 926 (Ala. 1998). "[W]arning of what [someone] already knew would have been futile." McGee v. Corometrics Medical Systems, Inc., 487 So. 2d 886, 894 (Ala. 1986). Thus plaintiff cannot assert warning claims about either the risk of additional surgery to remove instrumentation or the possibility of additional back pain – given her prior experience with precisely these risks.

Nor can plaintiff base any warning claim upon the rod remaining in her back after she achieved fusion. Because she stopped seeing Dr. Faulkner, her own conduct precludes causation. Plaintiff last visited Dr. Faulkner on August 20, 1997, before the rod broke. Faulkner Dep. at 46. At that time her fusion was not yet complete, so the device could not have been re-

moved. Id. at 46-47, 55. After August 20, 1997, plaintiff did not see Dr. Faulkner for more than three years – until October 11, 2000 – and by then she had achieved fusion and the rod had already broken. Id. at 50. This three-year gap means that Dr. Faulkner had no opportunity to consider removing the TSRH implant after fusion, but before it broke.

Indisputably plaintiff never saw Dr. Faulkner between August 1997 and October 2000. Thus, no warning to remove instrumentation after successful fusion could have made any difference. She never saw Dr. Faulkner when such a warning could have been relevant. Even if MSD had not warned at all about device removal following fusion (which MSD plainly did, see pp. 9-11, above), there could be no causation. Causation is an essential element of an AEMLD inadequate warning claim. Gurley v. American Honda Motor Co., 505 So. 2d 358, 361 (Ala. 1987); E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 963, 969 (Ala. 1985). Because plaintiff's three-year treatment gap prevented Dr. Faulkner from considering post-fusion device removal before the rod broke, no warning about that treatment option could have changed the outcome.

These two undisputed aspects of plaintiff's medical history – her prior experience with device removal after spinal fusion surgery, and the three years she did not see Dr. Faulkner – defeat her warning claims as a matter of law with no need to reach the additional bases for summary judgment provided by the learned intermediary rule. Having already suffered pain after spinal fusion surgery, and having already had additional surgery to remove prior instrumentation, plaintiff cannot claim ignorance of these risks. By stopping her medical treatment for three years, during the only time that a warning about device removal following fusion might have been acted upon, she cut any causal link between such a warning and her injuries.

2. Plaintiff's Warning Claim Fails As A Matter Of Law Under The Learned Intermediary Rule.

Alabama follows the learned intermediary rule. Stafford v. Nipp, 502 So. 2d 702, 704 (Ala. 1987); Stone, 447 So. 2d at 1304-05; Toole v. McClintock, 999 F.2d 1430, 1433 (11th Cir. 1993); Lansdell v. American Home Products Corp., 1999 WL 33548541, at *4-5 (N.D. Ala. Oct. 26, 1999). Under the learned intermediary rule, the duty to warn imposed upon a manufacturer of a prescription medical product "is limited to an obligation to advise the prescribing physician of any potential dangers that may result." Stone, 447 So. 2d at 1304.

> This special standard for prescription drugs is an understandable exception. . . . As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. . . . Pharmaceutical companies. . .in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Id. at 1305 (quoting Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974)). The learned intermediary rule extends to prescription medical devices as well as prescription drugs. Toole, 999 F.3d at 1432 (breast implants).

Under the learned intermediary rule, MSD is entitled to summary judgment for two separate reasons: (1) because MSD's warnings discuss the precise risks plaintiff allegedly encountered, they are adequate as a matter of law; and (2) there is no causation because Dr. Faulkner independently knew about those risks and did not rely upon MSD's warnings.

3. The Warnings In MSD's Package Insert Are Adequate As A Matter Of Law Because They Specifically Address The Risks At Issue In This Litigation.

As described in the Statement of Facts, at pp. 9-11, above, the TSRH package insert, Ritter Aff. at Ex. 2, specifically discusses the possibilities of broken rods, additional pain, and additional surgery. Possible component "failure" and "breakage" are specifically listed in the "Adverse Effects," "Warnings," and "Postoperative" sections of the insert. "Pain" is

referenced in the "Adverse Effects" and "Postoperative" sections. "Additional surgery" is mentioned in the "Adverse Effects" and "Warnings" sections. MSD even advises that "[t]he patient should be warned to avoid falls." Ritter Aff. at Ex. 2 (Package Insert) at "Postoperative," Item 1.

Further, MSD specifically advises surgeons that TSRH instrumentation should be "removed after the development of a solid fusion mass." Package Insert, at "Purpose"; id. at "Indications." Removal is indicated because "[a]fter healing occurs, these devices serve no functional purpose." Id. at "Postoperative." If the device is not removed after fusion is achieved "postoperative trauma," "breakage" and "development of pain" are possible "complications." Id.

A warning specifically addressing the claimed risk that a plaintiff encountered is "adequate, as a matter of law" and entitles the manufacturer to summary judgment. Gurley, 505 So. 2d at 361. In Gurley the warning "Operator only – No passengers" was legally adequate to inform even minors that only one person should ride on a motorcycle. Id. The warning defined the product's "intended use," establishing for purposes of summary judgment that "the practice of riding double is an unintended use." Id. Likewise Ex Parte Chevron Chemical Co., 720 So. 2d 922 (Ala. 1998), affirmed summary judgment against a warning claim where the defendant's instruction manual contained a "specific warning" about the risk (static electricity build up) that caused injury. Chevron, 720 So. 2d at 925-26.

Given MSD's extensive warnings, its entitlement to summary judgment here flows *a fortiori* from Gurley and Chevron. MSD's package insert expressly warned about component breakage, pain, additional surgery – even about falls. The "intended" use of the TSRH system was specifically stated (twice) to involve "remov[al] after the development of a solid

fusion mass." The risks of "postoperative trauma," component "breakage," and "pain" were all expressly linked to leaving the device in the spine after fusion occurred.[21]

Because MSD's warnings expressly address every device risk plaintiff encountered, they are adequate as a matter of law to apprise her learned intermediary, Dr. Faulkner, of those risks. Under Gurley and Chevron, MSD is entitled to summary judgment.

4. No Inadequacy In MSD's Warnings Caused Plaintiff's Injuries Because Dr. Faulkner Was Independently Aware Of All Relevant Risks And Did Not Read Or Rely Upon MSD's Warnings.

Dr. Faulkner is an extremely experienced surgeon with well over 1,000 instrumented spinal fusion surgeries to his credit before he performed plaintiff's operation. Faulkner Dep. at 10, 70. He chose the TSRH system, opted for the titanium model, and selected the components, including a "thicker rod" because of the "long fusion." Id. at 14, 19, 21, 23, 71.

Dr. Faulkner already knew all the relevant risks. He was aware that TSRH instrumentation could break, cause pain, and might require removal. Faulkner Dep. at 14-15, 57. Even with no break and successful fusion, pain or discomfort required removal of instrumentation in about 20% of patients. Id. at 65, 70, 96. Dr. Faulkner considered himself "adequately and appropriately informed" about the risks of TSRH instrumentation when he operated on plaintiff, and has learned nothing since that causes him to question anything he did. Id. at 10-11, 17, 28.

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[21]Dr. Faulkner disagreed with MSD's recommendation of routine implant removal after successful fusion, because 80% of patients, in his experience, never needed removal, and any additional surgery has risks. Faulkner Dep. at 65, 77. That disagreement, even if Dr. Faulkner could have acted upon it (see pp. 17-19, above), would not make MSD's warning defective. The Ninth Circuit recently held, on identical facts, that a disagreement in "medical judgment" did not render the manufacturer's warning inadequate:

> There isn't any evidence of record from which reasonable jurors could conclude that the warning was inadequate. It plainly said that the plate could break and that the manufacturer recommended removal. That physicians didn't follow the recommendation doesn't show that they couldn't or didn't read it and understand it, just that in their medical judgment, it wasn't wise to follow it.

Adams v. Synthes Spine Co., 298 F.3d 1114, 1118 (9th Cir. 2002) (affirming summary judgment; Washington law).

Dr. Faulkner did not rely upon MSD (or any manufacturer) for information about the risks of spinal instrumentation or, in particular, about how long such instrumentation lasts after implantation. Faulkner Dep. at 16-17, 61, 64. He had not read the MSD package insert "in years," and did not rely upon it. Id. at 25. Dr. Faulkner's sources of information were independent of MSD: his "training," "personal experience," "talk among peers," "medical books, textbooks," "journals," and "newsletters." Id. at 16-17.

Thus MSD is also entitled to summary judgment for lack of causation. There must be "some evidence that the allegedly inadequate warning would have been read and heeded and would have kept the accident from occurring." Gurley, 505 So. 2d at 361 (citation omitted). No matter what MSD's warnings said, Dr. Faulkner was fully aware of the relevant risks from independent sources and did not read or rely upon the MSD package insert. Dr. Faulkner's independent knowledge and non-reliance severed any causal link as a matter of law.

E.R. Squibb & Sons, Inc. v. Cox, 477 So. 2d 963 (Ala. 1985), involved a prescription drug, insulin. The plaintiff received a package insert from his pharmacy, but threw it away without reading it. As a matter of law, the plaintiff could not recover for inadequate warnings. The plaintiff was a literate English speaker, thus "nothing in the nature of [defendant's] inadequate[22] warning prevented plaintiff from reading it." Squibb, 477 So. 2d at 970. Failure to read the purportedly inadequate package insert precluded a finding of causation:

> . . .[N]o amount of specificity would have protected this plaintiff, because he would not have read a warning. Thus the presumed inadequacy of [defendant's] warning did not proximately cause plaintiff's injury.
>
> . . .[W]e hold today that a plaintiff who does not read an allegedly inadequate warning cannot maintain a negligent-failure-to-adequately-warn action unless the nature of the alleged inadequacy is such that it prevents him from reading it.

[22]The court "assume[d]" the warnings were inadequate "for purposes of this discussion." Id. at 970.

Id. at 971. Squibb thus stands for the proposition that "a plaintiff cannot maintain a failure-to-warn action where he simply chooses not to read a legible warning." Chevron, 720 So. 2d at 926 n.3 (affirming summary judgment). Nothing prevented Dr. Faulkner from consulting the MSD package insert in this case. Dr. Faulkner simply relied upon other, independent sources.

Nor can plaintiff point to any material risk that Dr. Faulkner did not know beforehand from independent sources. As discussed above, at p. 24, under Alabama law there is no duty to warn anyone about what he or she already knows. Thus MSD is entitled to summary judgment against plaintiff's warning claims because Dr. Faulkner's non-reliance and independent knowledge defeat the essential element of proximate cause.

D. Plaintiff's New Warranty Claims Cannot Defeat Summary Judgment.

Plaintiff recently filed an amendment to her complaint (attached as Exhibit I) adding claims for breach of: (1) implied warranties of merchantability and fitness for a particular purpose, and (2) unidentified "express warranties." These claims also fail as a matter of law.

1. The Statute Of Limitations Bars Plaintiff's Warranty Claims.

The TSRH rod at issue was implanted on November 13, 1996. Faulkner Dep. at 43. Plaintiff commenced suit on December 14, 2001, and filed her amendment to add warranty claims on October 17, 2002. Because the statute of limitations for warranty claims is four years from delivery, with no discovery rule, plaintiff's warranty claims are time barred.

The Alabama statute of limitations for breach of a warranty concerning goods is four years. Code of Ala. §7-2-725. There is no discovery rule, rather §7-2-725(2) expressly provides that "[a] cause of action for breach of contract accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made." Under this standard, the four-year statutory period runs from "the

time of the breach of the agreement rather than [from] the time that the actual damages are sustained as a consequence of the breach." Stephens v. Creel, 429 So. 2d 278, 280 (Ala. 1983).

The four-year warranty statute of limitations applies to personal injury actions. Bullen v. Roto Finishing Systems, 435 So. 2d 1256, 1258 (Ala. 1983); Wright v. Cutler-Hammer, Inc., 358 So. 2d 444, 446 (Ala. 1978). There is a statutory exception for personal injury claims involving "consumer goods,"[23] however, that exception does not apply here. Courts have repeatedly held that prescription-only medical devices are not "consumer" goods because they "are not customarily available to the ordinary person." Kemp v. Pfizer, Inc., 835 F. Supp. 1015, 1024-25 (E.D. Mich. 1993). Whether the supposed "consumer" is the patient or the physician, and whether the statute is state or federal, ordinary "consumers" cannot freely obtain prescription surgical implants the way they get "consumer goods."[24]

Where, as here, the product at issue is not a "consumer good," then the "case falls under the general limitations stated in the statute. . ., the action accrues upon tender of delivery of the [product], and this is so 'regardless of the aggrieved party's lack of knowledge of the breach.'" Wright, 358 So. 2d at 446 (rejecting application of tort statute of limitations to warranty-based product liability claims) (quoting §7-2-725(2)). Here, the TSRH Rod was "delivered" no later than November 13, 1996, when it was implanted in plaintiff. Plaintiff did not file suit until more than five years later. Consequently plaintiff's claims for breach of implied and express warranties are barred by the applicable four-year warranty statute of limitations.

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[23]Section 7-2-725 provides, "however, a cause of action for damages for injury to the person in the case of consumer goods shall accrue when the injury occurs."

[24]See Balderston v. Medtronic Sofamor Danek, Inc., 285 F.3d 238, 242 (3d Cir. 2002) (surgical implants not purchased for "personal, family or household use" under state consumer protection statute); In re Minnesota Breast Implant Litigation, 36 F. Supp. 2d 863, 876 (D. Minn. 1998) (surgical implants not "consumer products" under Magnuson Moss Act); Goldsmith v. Mentor Corp., 913 F. Supp. 56, 63 (D.N.H. 1995) (same); cf., Kanter v. Warner-Lambert Co., 122 Cal. Rptr. 2d 72, 86 (Cal. App. 2002) (same rationale for prescription drug).

2. The AEMLD Subsumes Plaintiff's Warranty Claims, So MSD Is Entitled To Summary Judgment For All The Reasons Previously Stated.

Regardless of the statute of limitations, MSD is entitled to summary judgment against plaintiff's warranty claims. Those claims are subsumed by the AEMLD, and thus fail for the same reasons as plaintiff's AEMLD claim. Personal injury claims concerning a purported unreasonably dangerous product sound under the AEMLD – not in breach of warranty:

> Whether this product was unreasonably dangerous, therefore, is not a question properly addressed in an action brought under the provisions of the U.C.C. That question could properly be raised in an action brought under Alabama's Extended Manufacturer's Liability Doctrine (A.E.M.L.D.), but not in this U.C.C. action for breach of warranty.

Shell v. Union Oil Co., 489 So. 2d 569, 571 (Ala. 1986); see Yarborough v. Sears, Roebuck & Co., 628 So. 2d 478, 483 (Ala. 1993) (breach of warranty claim asserted in product liability action "ignores the clear distinction between causes of action arising under tort law and those arising under the U.C.C. as adopted in Alabama").[25]

Under this controlling precedent, this and other federal courts applying Alabama law have held that breach of warranty claims in product liability cases are subsumed and governed by the AEMLD, and that such warranty claims have no separate significance. Brock v. Baxter Healthcare Corp., 96 F. Supp. 2d 1352, 1356 n.2 (S.D. Ala. 2000); Johnson v. GMC, 82 F. Supp. 2d 1326, 1328-29 (S.D. Ala. 1997); Webb v. Ashland Chemical, Inc., 1999 WL 33574650, at *2 (N.D. Ala. Jun. 7, 1999).

[25] Accord Pfizer Inc. v. Farsian, 682 So. 2d 405, 407 (Ala. 1996) ("[r]egardless of how [plaintiff] pleads his [warranty] claim, his claim is in substance a product liability/personal-injury claim."); Veal v. Teleflex, Inc., 586 So. 2d 188, 190-91 (Ala. 1991) (trial court properly refused to charge jury on claims other than the AEMLD in a product liability case).

Plaintiff's own cursory allegations fully justify treating her warranty claims as having no independent significance. Her merchantability claim (Ex. I ¶¶12-71) is entirely boilerplate – lacking any factual allegations separate from her AEMLD claim. Plaintiff's express warranty claim (id. ¶¶25-29) nowhere specifies what the purported express warranty says. Both her fitness for a particular purpose and express warranty counts allege reliance by Dr. Faulkner (id. ¶¶19, 27), but Dr. Faulkner's undisputed testimony establishes his non-reliance. See, above at p._. Plaintiff claims the rod was warranted to last "forever" (Ex. I ¶¶23, 25), but MSD's warnings and Dr. Faulkner's testimony – both also discussed above at pp. 8-11 – establish that MSD made no such claim. MSD is thus entitled to summary judgment against plaintiff's recently added warranty claims.[26]

CONCLUSION

For all of the above reasons, defendants are entitled to summary judgment because: (1) plaintiff cannot establish that the TSRH rod was improperly prepared; (2) plaintiff's conduct and knowledge precludes warning liability; (3) under the learned intermediary rule, MSD's warnings were adequate as a matter of law; (4) Dr. Faulkner's independent knowledge and lack of reliance rendered MSD's warnings non-causal; and (5) plaintiff's warranty claims are time barred and add nothing to her warning claim.

[26]Plaintiff also claims that unidentified warranties were made through the FDA approval process. Ex. I ¶¶26-27. To the extent plaintiff is claiming that MSD is liable for making false statements to the FDA, the claim is also preempted. Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) (holding all claims for "fraud on the FDA" are impliedly preempted by federal law).

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Dated: 12/3/2002

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing has been served upon counsel of record addressed as follows:

Paul R. Cooper, Esquire
312 Scott Street
Montgomery, AL 36104

by placing same in the United States mail, postage prepaid, on this 3rd day of December, 2002.

OF COUNSEL

EXHIBITS TOO LARGE FOR SCANNING-SEE ORIGINAL FILE